Remarks

Claims 1, 3-7, 9-12, 17, 19-21, 23, 24, 36-38, 41-58, 61, 63, 69, 71-73, 76, 81, 96 and 100-104 were pending in the application. Claims 100 and 101 are canceled. No claims are added. Thus, upon entry of this amendment, **claims 1, 3-7, 9-12, 17, 19-21, 23, 24, 36-38, 41-58, 61, 63, 69, 71-73, 76, 81, 96 and 102-104 will be pending**; of these, claims 7, 9, 10, 12, 20, 21, 36, 37, 42-44, 46-58, 61, 63, 69, 71-73, 76, and 81 are withdrawn.

Support for the amendments to claim 1 and 102 can be found throughout the specification, for example, page 9, lines 1-3; page 10, lines 6-8; page 21, lines 20-23; and page 22 lines 14-16. The remaining claims were amended for antecedent basis due to the amendments to claim 1.

SUMMARY OF TELEPHONE INTERVIEW WITH EXAMINER

Applicants thank Examiners Ha for the courtesy of a telephone interview on May 28, 2009 with Applicants' representative Sheree Lynn Rybak. During this interview, the 35 U.S.C. §§ 102(b) and 102(e) rejections were discussed. Although agreement was not reached, Examiner Ha suggested amending claim 1 to recite a composition, and to make it clear that the composition was at a physiological pH and contained a physiological salt concentration (and not merely that the peptide had particular properties under these conditions). Applicants also agreed to remove the non-elected peptide (P11-5) from the claims.

OBJECTION TO CLAIMS

Claims 1, 3-6, 11, 17, 19, 23, 24, 38, 41, 45, 96, and 102-104 are objected to as reciting a nonelected invention. Applicants have amended claim 1 and cancelled claim 101, which recited nonelected peptide P11-5. In view of this amendment, Applicants request that the claim objection be withdrawn.

REJECTION UNDER 35 U.S.C. §102

Claims 1, 3-6, 11, 17, 19, 23, 24, 38, 41, 45, 96, 100 and 103-104 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Aggeli *et al.* (*Peptide Science – Present and Future*, 1999, 30-33). Applicants disagree and request reconsideration.

To further clarify the claims, claim 1 is amended to recite a composition that includes peptide P11-3, wherein the composition contains a physiological concentration of salt, is at a physiological pH, and contains greater than 15 mg/ml of the P11-3 peptide. Claim 102 is similar, but recites that the peptide concentration is 15 mg/ml to 35 mg/ml. The remainder of the rejected claims depend directly or indirectly from claim 1.

In contrast to the pending claims, Aggeli *et al.* teach compositions containing P11-3 (referred to in Aggeli *et al.* as DN1-2E). However, no composition in Aggeli *et al.* containing P11-3 was at a physiological salt concentration, physiological pH, nor had a concentration greater than 15 mg/ml of P11-3. In contrast to the assertions of the Office on page 5 of the action, Aggeli *et al.* do not teach a phosphate buffer at physiological salt conditions. There is no NaCl present in the phosphate buffer described in Figure 3 of the Aggeli *et al.* reference. Applicants previously provided a declaration asserting this fact. The phosphate buffer has sodium phosphate but not sodium chloride. Thus the ionic strength of the buffer described in Figure 3 of Aggeli *et al.* is not physiological. The peptide is in a solution of 10 mM sodium phosphate in pure water (there is nothing else in this solution apart from peptide, pure water and 10 mM sodium phosphate; therefore this is not a physiological solution in terms of the salt, and salt concentration present in it). Thus the observations disclosed in Aggeli *et al.* do not teach anything regarding the presence of P11-3 in a composition having physiological pH and physiological salt concentration, which is the subject of the pending claims.

Furthermore, the P11-3 compositions of Aggeli *et al.* did not contain P11-3 at a concentration of greater than 15 mg/ml. In Aggeli *et al.*, P11-3 was at a concentration of 110 μM or 260 μM (which is 0.1706 mg/ml or 0.403 mg/ml, respectively) in the composition. In contrast, the claims recite significantly higher concentrations of P11-3.

Thus, because Aggeli *et al.* do not teach each and every limitation of the pending claims, the claims are not anticipated. Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §102(b).

REJECTION UNDER 35 U.S.C. §§102(e) and 102(a)

Claims 1, 3-6, 11, 17, 19, 23, 24, 38, 41, 100 and 103 are rejected under 35 U.S.C. §§102(e) and 102(a) as allegedly anticipated by Aggeli *et al.* (WO 2003/006494). Applicants disagree and request reconsideration.

To further clarify the claims, claim 1 is amended to recite a composition that includes peptide P11-3, a physiological concentration of salt, greater than 15 mg/ml of the P11-3 peptide, and wherein the composition is at a physiological pH. Claim 102 is similar, but recites that the peptide concentration is 15 mg/ml to 35 mg/ml. The remainder of the rejected claims depend directly or indirectly from claim 1.

WO 2003/006494 does not provide a composition that includes greater than 15 mg/ml of the P11-3 peptide. Thus, because WO 2003/006494 does not teach each and every limitation of the pending claims, the claims are not anticipated. Accordingly, Applicants request withdrawal of these rejections under 35 U.S.C. §§102(a) and 102(e).

REJECTION UNDER 35 U.S.C. §103

Claims 1, 3-6, 11, 17, 19, 23, 24, 38, 41, 45, 96, 100 and 103-104 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Aggeli *et al.* (*Peptide Science – Present and Future*, 1999, 30-33) as evidenced by biowww.net. Applicants disagree and request reconsideration.

Claim 1 recites that the P11-3 peptide is present at a concentration of greater than 15 mg/ml in the composition. Claim 102 recites that the peptide concentration is 15 mg/ml to 35 mg/ml. The remainder of the rejected claims depend directly or indirectly from claim 1.

There is no teaching or suggestion in the cited Aggeli *et al.* reference of the importance of the peptide concentration. In contrast, it is shown in the present application that the concentration of the peptide (*e.g.*, P11-3) in the composition is important to forming the composition (see page 9, lines 1-3; page 10, lines 6-8; page 21, lines 20-23; and page 22, lines 14-16). For example, as stated on page 9, lines 1-3, "The time it takes to reform depends on the peptide concentration, ranging from seconds for a 35 mg/ml peptide gel, to hours for a 15 mg/ml peptide gel." In addition, as stated on page 10, lines 6-7 "The peptide gels are formed with a very low peptide concentration (typically above 15 mg/ml), which corresponds to 0.01 volume fraction of peptide and 0.99 volume fraction of solvent in the gel, which means that the gels contain mainly solvent. Thus, encapsulated cells in these gels, have a lot of room available to grow, to communicate with each other and nutrients, oxygen, and various metabolites can diffuse almost freely in and out of the gel network." From the teachings in the cited Aggeli *et al.*

reference, one skilled in the art could not have predicted these effects of peptide concentration in the composition.

Furthermore, the WO 2003/006494 publication does not render the pending claims obvious, as there is no teaching or suggestion therein to the importance of peptide concentration in the composition.

Thus, because the Aggeli *et al.* reference (nor the WO 2003/006494 publication) does not teach or suggest the importance of peptide concentration in the composition, the claims are patentable in view of the cited art. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. §103 (a).

CONSIDERATION OF ADDITIONAL SPECIES

As generic claim 1 is in condition for allowance, Applicants request that additional species be examined at this time, pursuant to 37 C.F.R. § 1.141.

CONCLUDING STATEMENT

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Withdrawal of the pending rejections and reconsideration of the claims is respectfully requested. If the Examiner believes that there are any remaining issues in the case that could be resolved by a telephonic interview, the Examiner is encouraged to contact the undersigned to discuss any outstanding matters.

Respectfully submitted,

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